EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No.: 2327

THIS DOCUMENT RELATES TO:

KIMBERLY RANEY V. ETHICON LLC, ET AL

Civil Action No.: 2:13-cv-21784

RULE 26 CASE SPECIFIC EXPERT REPORT OF KONSTANTIN WALMSLEY, M.D.

I am Dr. Konstantin Walmsley. Any medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. All opinions are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature.

I. QUALIFICATIONS

I am a licensed physician in the State of New Jersey and a board-certified urologist. I am familiar with the evaluation and treatment of pelvic organ prolapse and stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Specifically, I am familiar with Ethicon, Inc.'s ("Ethicon") products, including but not limited to the TVT-Secur device. I have implanted these devices in my patients. I have attended training provided by mesh manufacturers, including Ethicon, regarding these devices. I have reviewed the IFU's for the

Ethicon products and reviewed the independent medical literature. Additionally, I have explanted mesh and performed other revision procedures on SUI and POP kits.

In light of my training, knowledge, experience, and qualifications set forth above and in the attached CV, I am familiar with the standards of care applicable in the jurisdiction where the Plaintiff resides as to surgical technique for implantation of the below-referenced Ethicon devices.

Additionally, because of my training, knowledge, experience, and qualifications as set forth above and in the attached CV, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, incomplete emptying, and urinary retention), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients' complications based upon a review of her medical records and knowledge of her prior medical history.

A copy of my CV is attached as Exhibit "A", and a copy of my testimony for the last four years and Fee Schedule is attached as Exhibit "B". The documents I relied upon for this report are contained in Exhibit "C" as well as those documents cited throughout this report.

II. SUMMARY OF CASE SPECIFIC OPINIONS

In formulating my opinions and preparing this report, I have reviewed all available medical records in this case. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand that discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions, and the expert reports of both Plaintiff and Defense experts. In formulating my opinions herein, I also relied upon my clinical experience in treating SUI.

It is my opinion, to a reasonable degree of medical and scientific certainty, that the debilitating injuries Ms. Raney suffered, some of which are discussed below, and the majority of her post-implant medical course are a direct result of implanting the Ethicon TVT-Secur sling device. As discussed in prior general liability reports, the mesh products are not suitable for their intended application as a permanent prosthetic implants for the treatment of stress urinary incontinence (SUI) because of the following characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never intended to be implanted inside the pelvic cavity and resultant incompatibility with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices.

As a result, these mesh devices are not suitable for their intended applications as permanent prosthetic implants for pelvic floor repair in women, such as Ms. Raney. Ethicon failed to act as a reasonable and prudent medical device manufacturer by manufacturing and

selling its polypropylene mesh in permanent implants like their TVT-Secur devices. As a result of these and other inadequacies, it is my opinion to a reasonable degree of medical certainty that the implantation of these devices caused Ms. Raney to suffer injuries which are permanent in nature. These injuries include: continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring.

The medical treatment required to treat Ms. Raney's injuries caused by the mesh products were a foreseeable result of her complications. In formulating my opinions and preparing this report, I considered the scientific literature, corporate documents from Ethicon, and case-specific materials such as medical records and available deposition testimony in this matter. I further considered my own clinical experience in treating stress urinary incontinence in my practice. The corporate documents have been reviewed by me during preparation of prior reports relating to polypropylene mesh used for SUI and pelvic organ prolapse (POP). I have also relied upon the Ethicon TVT-Secur General Causation reports authored by Dr. Jerry Blaivas and Dr. Daniel Elliott. All opinions I have offered are held to a reasonable degree of medical and scientific certainty.

III. CASE SUMMARY

Throughout my analysis of Ms. Raney's conditions, I have relied upon her medical records and medical history to date. Her medical history is outlined as follows:

At the time of implant, Ms. Raney (January 4th, 1966) was a 41- year-old gravida 3, para 3 patient. Her three births were vaginal deliveries. Her past medical history was remarkable in part for anemia, thyroid disease, prediabetes, obesity, and migraines. Her prior surgical history was remarkable in part for Novasure endometrial ablation and bilateral tubal ligation. She was a non-smoker.

On 2/5/07, given the diagnosis of stress urinary incontinence (SUI) due to urethral hypermobility, Dr. Chad Caudill placed a TVT-Secur sling in Ms. Raney.

On 10/10/07, due to dyspareunia from Dr. Caudill removed some exposed TVT-Secur mesh from Ms. Raney's vagina via "office trimming."

On 6/28/11, given the diagnosis of recurrent SUI, Dr. Caudill placed a Boston-Scientific Obtryx sling via a transobdurator approach.

On 3/28/13, Dr. Chad Caudill removed exposed TVT-Secur mesh from Ms. Raney's anterior vaginal wall.

On 6/23/14, Ms. Raney was admitted to Mercy Hospital for surgery to help correct vaginal and pelvic pain and voiding dysfunction. Her preoperative history and physical memorializes recurrent extrusion events from both the TVT-Secur and Boston Scientific Obrtyx meshes following their implantations. Ms. Raney also complained of dyspareunia, SUI, and pelvic pain severe enough to limit her ability to work. She also described an uncomfortable poking sensation in the midline of her vagina. Physical exam revealed that the sling was palpable and tender bilaterally, left greater than right. Given the diagnoses of vaginal pain and dyspareunia, Ms. Raney underwent removal of the TVT-Secur sling and the Boston Scientific Obtryx sling, urethrolysis, paravaginal repair and vaginoplasty with Drs. Dionysius Veronikis and Sara Wood.

On 9/29/14, given the diagnoses of cystocele, rectocele, and recurrent SUI, Dr. Wood performed anterior and posterior colporraphy, sling urethropexy using a Caldera sling, and suprapubic tube placement.

On 9/23/15, Ms. Raney saw Dr. Veronikis with complaints of mesh problems. Specifically, Ms. Raney complained of constant pelvic pain worsened with sitting and walking,

and dyspareunia. She described "pain with walking that hurt in the tendon and radiates to the pelvis lateral to the clitoris towards the leg." Genitourinary exam revealed a perineal skin bridge as well as pain on palpation of the obdurator muscles, particularly on the left.

IV. CASE SPECIFIC EXPERT OPINIONS

Ms. Raney was implanted with Ethicon's TVT-Secur device on 2/5/2007, and to a reasonable degree of medical and scientific certainty, this device caused her injuries. Ms. Raney should not have been implanted with the Ethicon TVT-Secur sling because the poor design of the device increased the risk of serious complications and caused her specific complications. These complications include, but are not limited to: continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury and then, by process of elimination, "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis or differential etiology and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case. In general, my expert opinions can be summarized as follows:

A. Ethicon's construction mesh, used in the TVT-Secur device, is not suitable for its intended application as permanent prosthetic implants for stress urinary incontinence because the pores are too small, it is a heavy weight mesh, it degrades over time, and it can cause chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections; in addition, the mesh has sharp edges, and has been found to rope, curl, and deform. Under tension, the pores have been found to collapse. The TVT-Secur

mesh has particularly sharp mesh edges due to its laser-cut preparation, different than the TVT-classic preparation by comparison.

B. Ethicon knew that its TVT-Secur mesh device was not appropriate for use, but it failed to modify/change the mesh to a larger pore size or a lighter weight mesh that would be less likely to degrade, cause excessive foreign body reactions or chronic inflammation, or deform, become rigid, fray, rope, or cord after implantation, and cause the formation of fibrotic bridging that leads to scar plate formation and mesh encapsulation, which makes these devices difficult if not impossible to remove. According to Ethicon's internal documents, it was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon put profits before patient safety.

C. Ethicon's TVT-Secur device has design flaws because they cannot adequately describe, inform, or explain to physicians how to properly "tension" the device. Further, the devices shrink, contract, rope, and curl making it difficult or impossible to tension in a safe manner for patients.

D. Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ("MSDS") for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina.

E. Ethicon's mesh devices are also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications.

F. Ethicon's warnings and disclosures of adverse events in their Instructions for Use ("IFU") for these devices have been inadequate based on the adverse reactions and risks

associated with them that have been known to Ethicon from the time these devices were first sold and marketed. Ethicon did not disclose information to physicians in their IFU regarding characteristics of their devices that makes them unsuitable for their intended application as a permanent prosthetic implant for pelvic floor repair. This includes - small pore size; heavy weight mesh; the mesh's tendency to degrade over time which causes chronic foreign body reactions, fibrotic bridging, contraction, shrinkage, fraying, loss of particles, roping, curling, or deform; the pores collapsing with tension; the mesh becoming difficult or impossible to remove; the mesh testing positive for cytotoxicity; and, the MSDS stating that it is incompatible with strong oxidizers, such as peroxides.

G. The design of these devices are flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.

H. Ethicon failed to reveal material facts about complications and conflicts of interest regarding key studies in key marketing documents.

I. The benefits of these mesh products are outweighed by the severe, debilitating, and life changing complications associated with them and there were safer alternative options available.

J. As a result of the defects in these meshes, Ms. Raney suffered and continues to suffer life-long injuries.

1. Based on my background, education, training, and experience, as well as the medical records and available deposition testimony offered in this case, it is my opinion that Dr. Caudill's treatment of Ms. Raney met the standard of care. The pre-operative evaluations of the patient met the standard of care. The TVT-Secur sling was implanted due to complaints of

stress urinary incontinence (SUI); and surgery was performed within the standard of care with no evidence of surgeon error or deviation from the manufacturer's procedural steps enumerated in the IFU. Similarly, it is my opinion that the subsequent care and treatment provided to Ms. Raney by Ms. Raney's healthcare providers, including but not limited to Drs. Caudill, Wood, and Veronikis met the standard of care. The pre-operative evaluation of the patient met the standard of care. The mesh excision procedures were indicated due to the TVT-S causing Ms. Raney's pelvic pain and dyspareunia were performed within the standard of care, with no evidence of surgeon error or deviation from the standard of care for treating mesh-related erosions and associated complications.

After implant of the TVT-Secur sling, Ms. Raney developed continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring. The small pore size, heavy weight mesh, degradation, chronic foreign body response, fibrotic bridging, contracting and shrinking, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the collapsing of pores within the Ethicon TVT-Secur mesh caused these symptoms. Furthermore, her symptoms of continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring are consistent with known complications such as those described above and is associated with and caused by these mesh products. To a reasonable degree of medical certainty, the mesh implanted and its effects on the surrounding tissues are the causes of Ms. Raney's injuries, which have been outlined in this report.

Ms. Raney's complaints following the TVT-Secur implantation are remarkable for continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring. The timing of the symptoms, the severity and continual nature

of the symptoms, combined with the nature of her conditions provide the relevant information regarding the differential diagnosis.

I did consider her past medical history which included: she was a gravida 3, para 2 patient. All births were vaginal deliveries. Her past medical history was remarkable for anemia, thyroid disease, prediabetes, obesity, and migraines. Her prior surgical history was remarkable in part for Novasure endometrial ablation and bilateral tubal ligation. She was a non-smoker. Ms. Raney's symptoms of pelvic pain, vaginal pain, dyspareunia, and voiding dysfunction all markedly worsened after her TVT-Secur sling was placed. Her symptoms were also associated with the TVT-Secur by her healthcare providers, based on their examinations and treatment of her.

To a reasonable degree of medical certainty, the small pore size, the heavy weight mesh, degradation over time, chronic foreign body reactions, fibrotic bridging, mesh contracture and shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the pore collapsing with tension of the meshes implanted caused Ms. Raney's symptomatology. It is my opinion that she may suffer from long term risks of voiding dysfunction and pelvic pain originally caused by the TVT-Secur. As a result, Ms. Raney may need additional surgeries and treatment to treat vaginal scarring, pelvic pain, incontinence, and voiding dysfunction associated with the original implantation of the device. Ms. Raney may also require pelvic floor therapy, physical therapy, and other procedures to alleviate her symptoms which stem from the implant of the TVT-S.

Based on my review of the entire body of literature, my experience, review of Ms. Raney's medical records and her deposition testimony provided to me by counsel, it is my opinion, to a reasonable degree of medical certainty, Ms. Raney would not have developed the

aforementioned symptoms, or the need to undergo additional treatments to the extent that she has, had the Ethicon TVT-Secur sling had never been implanted.

It is my opinion that there were reasonably feasible alternatives available to Ethicon's mesh devices, and for the treatment of Ms. Raney. Even other lightweight meshes would have been a safer alternative to the Ethicon mesh implanted in Ms. Raney.

Safer alternative designs, rather than TVT-Secur, a polypropylene mesh laser-cut product, existed for this patient. I have experience with many of these safer alternative designs and based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Ms. Raney. These safer alternative designs include:

(1) the use of sutures, including delayed absorbable sutures like PDS, in a Burch colposuspension for SUI;

(2) autologous fascia sling;

(3) an allograft sling repair with product such as certain biological graft materials; and

(4) a sling repair with less polypropylene such as Ultrapro.

These safer alternative designs were capable of preventing Ms. Raney's injuries and damages, as I have described in my report, that were a result of the specific design flaws of the Ethicon TVT-Secur device using Marlex polypropylene, including degradation, cytotoxicity, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges. If any of these safer alternative designs been used for Ms. Raney, she would not have suffered the injuries I set forth in my report, as her injuries were caused by the specific design flaws of the Ethicon TVT-Secur device discussed above and in my general reports. The likelihood that the Ethicon TVT-Secur

design would cause Ms. Raney's injuries and damages and the gravity of those injuries and damages outweighed the burden on Ethicon of adopting such alternative designs and the adverse effects, if any, of such alternative designs on the utility of the Ethicon TVT-Secur product. The inadequate warnings about the Ethicon TVT-Secur device significantly increased the likelihood of injuries and damages to Ms. Raney, and caused or contributed to cause the injuries and damages to Ms. Raney. Ethicon failed to use reasonable care to provide adequate warnings to users and handlers of the Ethicon TVT-Secur device, as discussed herein.

Also, as discussed in the general reports I've reviewed and in my own clinical experience using the Ethicon TVT-Secur device, Ethicon failed to include and/or describe the significant adverse events and risks in its IFU for these devices. Ethicon did not fully inform physicians about the numerous adverse reactions/risks associated with these devices despite the fact that Ethicon had scientific knowledge of the risks from the time these products were first sold. As a result, physicians, including Ms. Raney's implanting physician, were unable to fully consent and inform patients of the risk associated with these products. In addition, some risks included by Ethicon in the IFU were mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals, Ethicon did not make the necessary updates.

To a reasonable degree of medical certainty, this prevented physicians and patients from having the ability to make an informed choice regarding the use of the Ethicon TVT-Secur device. For a surgeon to properly inform the patient of all the known risks included in any procedure involving an implantable medical device the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the "Adverse Events/Risks" section of a

medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.

For these reasons, and as fully outlined in general reports, review of relevant literature, and my own clinical experience, Ethicon failed to advise Ms. Raney's implanting physician of the adverse events and risks associated with the Ethicon TVT-Secur device. Ms. Raney's implanting physician, Dr. Caudill, was not fully able to consent her for the procedure because he was not fully aware of what would happen after the TVT-Secur was implanted.

Ms. Raney's implanting physician, Dr. Caudill, did not know about many of these risks prior to implanting her with these devices. Ethicon had knowledge of these risks and therefore, they should have included them in the IFU so that Dr. Caudill could perform an appropriate risk-benefit analysis. As a result, to a reasonable degree of medical certainty, it is my opinion Ms. Caudill was damaged by the injuries she suffered that were not disclosed to her implanting physician by Ethicon.

VI. CONCLUSION

To a reasonable degree of medical certainty, it is my opinion that the Ethicon TVT-Secur device caused Ms. Caudill's conditions including continued and worsening urinary incontinence, pelvic pain, vaginal pain, mesh extrusion/erosion, dyspareunia, and vaginal scarring.. In addition, it is my opinion to a reasonable degree of medical certainty she will experience continued and ongoing complications and need additional medical treatments in the future related to the permanent complications she suffered from the inadequacies and implantation of the Ethicon TVT-Secur sling. I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this September 9th , 2019.

Sincerely,

Konstantin Walmsley, M.D.

My standard rate is $500/hour for expert witness related work and testimony. For out-of-state work requiring an overnight stay, my standard rate is $5000/day.